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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,845	06/27/2003	Patricia Arand	354458002US3	7100

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EXAMINER	
ALTER, ALYSSA M	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,845	ARAND ET AL.	
	Examiner	Art Unit	
	Alyssa M Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> ((e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-4, 7, 10-11, 15-19, 21-30, 32, 34-35, 37-38, 40-49 and 51-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Duff et al. (US 4,905,706). Duff et al. discloses a method and apparatus for detection of heart disease with phonocardiogram (PCG) sounds and electrocardiogram (ECG) signals. "The digitized ECG signal is transmitted to processor 22, where it is used to correlate the PCG signal with specific heart sounds" (col. 3, lines 18-20).

As to claims 2, 10-11, 18-19, 23-24, 28-29 and 48-49, "the first heart sound is caused by the closure of the atrioventricular valves (the tricuspid valve and the bicuspid or mitral valve) and the contraction of the ventricles. After a brief interval, a second rapid heart sound S2 appears, caused by the closing of the aortic and pulmonary valves. Diastolic blood flow begins after the second heart sound, resulting in a third heart sound S3"(col. 4, lines 7-14). "The diastolic window beginning about 112 milliseconds after the peak of the second heart sound and lasting about 133

milliseconds" (col. 4, lines 40-43). The fourth heart sound also occurs after S2, within the window.

As to claims 7, 32, 34-35, 37-38, 41 and 46-47, "after the input data has been taken, the operator begins processing of the data by first selecting the number of heartbeats to analyze (54). The inventors have found that a minimum of nine heartbeats is desirable to insure accurate results. After entering this number, the operator next selects the ECG trigger level for identifying the R-wave of any given heartbeat (56). It is necessary to identify the R-wave in order to isolate the cardiac screening window of the PCG"(col. 5, lines 45-53). Also, "the operator then determines if the R-wave peak has been correctly identified (60). If not, processor 22 looks for a new peak. If so, the operator locates the starting point of the cardiac screening window (62), and the data for this window is put in temporary storage (64). Also, the counter which keeps track of the number of acceptable beats is incremented. This continues until the number of samples reaches the number previously input by the operator in step 54" (col. 6, lines 7-15).

As to claims 27, 30 and 40, since the "first heart sound S1 commences about the same time as the P-wave appears, and continues throughout the Q-R-S complex"(col. 4, lines 4-7), the PR interval is inherently identified. Also, "an average of the peak-to-peak amplitudes of the first and second heart sounds" (col. 6, lines 35-36) are calculated

As to claims 42, 44 and 51-54, "the bandpass filter 16 therefore passes only frequencies within this range, removing the large amount of energy contained in the

major heart sounds at frequencies less than 100 Hz, and attenuating any noise having frequencies above 600 Hz"(col. 2, lines 60-64). Therefore the heart sounds frequency between about 100 Hz and 600 Hz are utilized.

2. Claims 1-5, 7, 10, 14-29, 34, 39, 41-42, 44-46, 48-49 and 51-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Mai et al. (US 6,643,548). Mai et al. discloses an implantable cardiac stimulation device for monitoring heart sounds to detect progression and regression of heart disease.

As claims 1, 3-4, 15-17, 21-22 and 25-27, "a sensing circuit produces an electrogram signal indicative of the electrical activity of the patient's heart. A sound, or acoustic, sensor produces a phonocardiogram representing the sounds omitted from the patient's heart. A processor determines time intervals between selected heart sounds in the phonocardiogram and morphological features in electrogram. Relative changes in the time intervals or the amplitude, over time, are indicative of progression or regression in the heart disease. The time intervals and/or amplitudes are stored in a memory for later telemetry to an external receiver for review by medical personnel" (col. 2, lines 19-29). The examiner considers the time intervals to be the window.

As to clam 2, 5, 39 and 41, since the "time intervals may be time intervals between a heart sound and a morphological feature of a common cardiac cycle, such as an R-wave"(col. 2, lines 30-32), the window inherently starts approximately at the Q-onset, because R is part of the QRS complex. "The time intervals may more specifically be time spans between an R wave and an S1 heart sound and time spans between an S1 heart sound and an S2 heart sound"(col. 2, lines 35-37).

As to claims 7 and 28-29, "the average R to S1 and average S1 to S2 time intervals are then stored in memory for later telemetric retrieval. By noting relative changes in the average R to S1 and S1 to S2 time intervals over time, the progression or regression of congestive heart failure may be monitored" (col. 8, lines 47-52).

As to claims 10, 18-19, 23-24 and 48-49, "except for the occasional brief S3 and S4, diastole is normally silent. When diastolic murmurs occur, they are heard between S2 and S1 corresponding to the interval between the end of the T wave and the beginning of the QRS complex in the electrogram" (col. 8, lines 35-39).

As to claims 14 and 20, "the amplitude of S1 may be determined by determining the maximum of the heart sound signal between the located R wave and the located T wave"(col. 9, lines 58- 60). Like the amplitude of S1, the amplitude of S2 can also be determined.

As to claim 34 and 45-46, as seen in figure 4, the method used to determine the average time intervals from heart sounds and electrogram features sense the cardiac cycle and if all data is processed, the average time interval. If all the data is not processed, due to waves or sounds that were not detected, then the next cardiac cycle is analyzed. Figure 2 shows the morphological features of the cardiac cycle 200 and abnormal heart sounds 204 compared to the normal heart sounds 202.

As to claims 42, 44 and 51-54, "the signal conditioning circuit 112 includes a band pass filter which filters the raw heart sound signal from 10 Hz to 150 Hz"(col. 6, lines 24-26).

3. Claims 1-7, 10-11, 14-17, 20-22, 25-33, 39, 41-44, 50, and 51-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Schulhauser et al. (US 6,869,404). Schulhauser et al. discloses an apparatus and method for chronically monitoring heart sounds for deriving estimated blood pressure. An implantable heart sound and ECG monitor uses "subcutaneous ECG electrodes and a memory for storing ECG and heart sound data" (col. 4, lines 22-24). Also included in implanted device is a microprocessor for processing heart sound data.

As to claims 2-4, "a detected R-wave on a sensed ECG signal may be used to trigger sampling of the heart sound sensor signal for a specified period of time for detecting the first heart sound. A detected T-wave may be used to trigger sampling of the second heart sound signal"(col. 4, lines 24-28).

As to claim 5-6, 10-11, 39 and 41, the R-wave is detected and since the R wave is part of the QRS complex, the window inherently starts approximately at the Q-onset because R is part of the QRS complex. Also, "during the S1 and S2 sensing windows, input circuit 50 is enabled for receiving signals related to heart sounds received by heart sound sensor 22. S1 is typically on the order of 150 ms in duration, and S2 is typically on the order of 120 ms in duration. The associated sensing windows may therefore be set on the order of 100 to 200 ms, more preferably on the order of 150 ms in duration" (col. 10, lines 22-29). Therefore, the windows for sensing the sounds would inherently be the same as the sounds duration, thus making the S1 window approximately 150 ms and making the S2 window approximately 120 ms.

As to claims 7, 14, 20, 26, 30-33, 43 and 50, the examiner considers the power of the heart sound to be the amplitude. Therefore, the peak amplitude, average amplitude and the ratios of amplitudes and average amplitude are inherently calculated, as seen in Table 1 in column 12. Also seen in Table 1 is the total harmonic distortion (THD), which the examiner considers the signal to noise information, and average THD are calculated.

As to claims 27-29, since the average amplitudes of the sounds are calculated, the heart sound, S1 or S2, is inherently compared to an additional heart sound, S1 or S2 respectively, in order to calculate the average heart sound.

As to claims 42, 44 and 51-54, "the preamplifier output is provided as input to a bandpass filter 74, preferably tuned, via signal line 75, to pass a range of frequencies containing pertinent heart sound information. The first heart sound typically has a frequency on the order of 25 to 45 Hz and the second heart sound typically has frequency on the order of 50 Hz. Therefore bandpass filter 74 may be tuned to a range on the order of 10 Hz to 100 Hz, and more preferably to a range on the order of 20 Hz to 60 Hz, though systolic blood pressure estimation based on heart sound data collected below 32 Hz is feasible"(col. 9, lines 18-27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 8-9 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulhauser et al. (US 6,869,404). Schulhauser et al. discloses the claimed invention except for the window interval. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the time of the window interval, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

2. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duff et al. (US 4,905,706). Duff et al. discloses the claimed invention except for the percentage of total number of beats. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the total number of beats as taught by Duff et al. with a total percentage of beats since it was known in the art that percentages yield a uniform means of comparison.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Turcott (US 6,409,675) discloses an extravascular hemodynamic monitor.

2. Syed et al. (US Patent Publication 20040260188 A1) discloses an automated auscultation system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M. Alter

Alyssa M Alter
Examiner
Art Unit 3762

JEFFREY R. JASTRZAB
PRIMARY EXAMINER
4/18/05